Testimony of Curt D. Furberg, M.D., Ph.D.
Before the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
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Mr. Chairman and Members of the Committee,

My name is Curt Furberg. I am a professor of Public Health Sciences at the Wake Forest University School of Medicine, with expertise in drug evaluation and safety. I also serve as a member of the FDA Drug Safety & Risk Management Advisory Committee. This testimony reflects my personal views.

I am a firm believer in law and order. Congress has a critical role in developing and passing laws to protect what is right and fair. Laws and regulations are effective because violations have consequences! Our citizens cherish the notion that no one is above the law; therefore it troubles me that drug makers can violate FDA regulations, commitments and public trust without apparent consequences.

Here are some examples:

One company testing its antidepressant in adolescents reported and made public only three of its 13 trials. The other ten did not support the company's claim for efficacy and safety. Despite this suppression, the FDA has taken no action against the sponsor.

Another company delayed for several years submitting unfavorable safety data from a trial of its COX-2 inhibitor for Alzheimer's disease. The FDA has taken no action.

A third company submitted falsified data for an FDA hearing of its antibiotic, as discussed at your previous hearing on drug safety. Again, the FDA has taken no action against the company.

Thus, it appears that regulatory violations have no consequences in the U.S.

A fourth company "stalled" negotiations for 14 months over label changes that would add an important Black Box Warning for its COX-2 inhibitor. Decisions about label warnings should take only one to two weeks. This irresponsible delay in warning prescribers and the public about serious drug risks had no consequences for the drug maker.

These cases illustrate industry's malfeasance. They are alarming and have serious implications for public health. Tragically, they represent only a small fraction of the total problem. These examples pale in comparison to the potential public harm caused by industry's unmet commitments to conduct post-market safety trials. The approval of many new drugs is based on these commitments. As of last Fall, there were 1,259 unmet commitments with more than two-thirds of the safety trials not even initiated. What has the FDA done? Nothing!

In my view, it is critical for Congress to:

1. Provide the FDA with enforcement tools.
2. Give the FDA the legal authority to change drug labels and to withdraw unsafe drugs without negotiation.
3. Ensure through Congressional oversight that the FDA utilizes this new authority appropriately and in a timely manner.

I was asked to comment on the FDA's responses to the IOM recommendations. Overall I find them disappointing. Although many of the responses have merit, there are several shortcomings.

- First, the agency's apparent unwillingness to ask Congress for more authority to enforce safety regulations is troubling.

- Second, the FDA plan lacks concrete and constructive steps to bring drug safety to parity with drug benefit in the evaluation process. After all, decisions about drug approval and later use of a drug are based on the balance between benefit and harm. The Office of Surveillance and Epidemiology needs more experts in drug safety, public health and surveillance. The Director of this Office should report directly to the Commissioner and the Office should have its own external Advisory Committee.

- Third, another concern not addressed is the FDA's lack of transparency. Prescribers and the public are not given safety data known to FDA officials in a timely manner. The reasons for disapproving a new drug or the reasons for requesting post-marketing safety studies are kept secret.

- Fourth, also missing in FDA's response is an evaluation plan. Progress towards improvement of the drug safety problems needs to be closely monitored and reported, with corrective actions being taken if goals are not met.

- Finally, the measure of FDA's performance needs to be changed. It should not be based only on the number of drugs approved within certain time limits. Full credit should be given for disapproval of drugs for safety reasons.

There are additional problems highlighted in a recent article entitled "The FDA and Drug Safety -- A Proposal for Sweeping Changes," which I would like to attach to my testimony. This article was written by me and four other current and past members of the FDA Drug Safety & Risk Management Advisory Committee.

I. What are your concerns about PDUFA IV?

1. PDUFA has created an unhealthy relationship between the FDA and the industry that the FDA is supposed to regulate.

2. The dependence on the user fees has made the FDA more "accommodating" towards drug makers' requests. We have a clear conflict-of-interest situation.

3. The size of the user fee magnifies the problem.

4. The problem is compounded by the restricted use of the fees to meet industry's self-serving interests. For every $13.50 slated for approval reviews and general expenses, only $1 is allocated to post-market safety activities.

5. No other user fees have such restrictions on their use, only PDUFA.

6. Recent analyses have shown that the rush to meet approval deadlines and to qualify for payments has subsequently brought to the market drugs with an excess of unrecognized safety problems.

7. The number of serious adverse events reported to the FDA since PDUFA II was enacted has increased more than 2.5-fold.

8. PDUFA benefits the drug makers but the price is paid by an increasing number of innocent patients suffering serious adverse drug reactions.

I am in favor of closing out PDUFA over the next few years and replacing the budget shortfall with a normal prescription drug fee of 5 cents.

II. How can the use of potentially harmful drugs be reduced?

1. In two ways: First, by restricting the number of prescriptions. The right to prescribe the drug can be limited to physicians within certain specialties, prescribers can be required to undergo special training related to the drug, prescriptions could be restricted to patients who are refractory to safer treatment alternatives, and the duration of drug treatment could be limited.

2. The second way to reduce use of potential harmful drugs is through patient education. Patients (or their parents) could be given a Medication Guide when they pick up the drug in the Pharmacy, which fully explains the beneficial and harmful effects of a drug. They could also be asked to sign a form every time they fill the prescription. This would state that they are fully aware of all the risks of their prescribed medication. These steps tend to discourage use.